

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION**

POZEN INC. Plaintiff, v. PAR PHARMACEUTICAL, INC. Defendant.	CIVIL ACTION NO. 6:08-cv-437-LED PATENT CASE
POZEN INC. Plaintiff, v. ALPHAPHARM PTY LTD. Defendant.	CIVIL ACTION NO. 6:09-cv-003-LED CONSOLIDATED WITH CIVIL ACTION NO. 6:08-cv-437-LED AND CIVIL ACTION NO. 6:09-cv-182-LED PATENT CASE
POZEN INC. Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION NO. 6:09-cv-182-LED CONSOLIDATED WITH CIVIL ACTION NO. 6:08-cv-437-LED AND CIVIL ACTION NO. 6:09-cv-003-LED PATENT CASE
POZEN INC. Plaintiff, v. DR. REDDY'S LABORATORIES, INC. Defendant.	CIVIL ACTION NO. 6:08-cv-437-LED PATENT CASE

JOINT FINAL PRE-TRIAL ORDER

Pursuant to Local Rule CV-16 and Rule 16 of the Federal Rules of Civil Procedure, the parties submit the following Joint Final Pre-Trial Order.

A. COUNSEL FOR THE PARTIES

Plaintiff: Pozen Inc.

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Defendants: Par Pharmaceutical, Inc.; Alphapharm Pty Ltd.; and Dr. Reddy's Laboratories, Inc.

Michael E. Jones (Bar No. 10929400) and Allen F. Gardner (24043679), of POTTER MINTON; Richard J. Berman (Bar No. 76800 (Pennsylvania)), Janine A. Carlan (Bar No. 197613 (California)), Aziz Burgy (Bar No. 483517 (District of Columbia)), Amy E.L. Schoenhard (Bar No. 65914 (Virginia)), Timothy W. Bucknell (Bar No. 235098 (California)), Joshua T. Morris (Bar No. 73239 (Virginia)), and Taniel E. Anderson (Bar No. 78628 (South Carolina)), of ARENT FOX LLP, representing Defendant Par Pharmaceutical, Inc.

Deron R. Dacus (Bar No. 00790553) of RAMEY & FLOCK P.C.; Thomas J. Parker (Bar No. 2499846 (New York)) and Natalie C. Clayton (Bar No. 4409538 (New York)), of ALSTON & BIRD LLP, representing Defendant Alphapharm Pty Ltd.

Charles Ainsworth (Bar No. 00783521) and Robert Christopher Blunt (Bar No. 00787165) of PARKER, BUNT, & AINSWORTH P.C.; William L. Mentlik (Bar No. 22563 (New Jersey)), Paul H. Kochanski (Bar No. 01673 (New Jersey)), Michael H. Teschner (Bar No. 54465 (New Jersey)) and Stephen J. Brown (Bar No. 3893716 (New York)), of LERNER,

DAVID, LITTENBERG, KRUMHOLZ & MENTLIK, LLP, representing Defendant Dr. Reddy's Laboratories, Inc.

B. STATEMENT OF JURISDICTION

Jurisdiction in this case is based upon 28 U.S.C. §§ 1331 and 1338 in that the Plaintiff brings this action under the patent laws of the United States, including 35 U.S.C. § 271 *et seq.* Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(c), (d) and 1400(b). Jurisdiction is not disputed.

C. NATURE OF ACTION

This is a patent infringement case. Plaintiff Pozen Inc. ("Pozen") alleges that Defendants Par Pharmaceutical, Inc., ("Par") Alphapharm Pty Ltd. ("Alphapharm") and Dr. Reddy's Laboratories, Inc. ("DRL") directly infringe and/or indirectly infringe by inducing the infringement of Claim 15 (as dependent on Claim 5) of U.S. Patent No. 6,060,499 ("the '499 Patent") and Claims 11, 12, and 24 (as dependent on Claim 3) and 26, 27, 29, and 30 of U.S. Patent No. 6,586,458 ("the '458 Patent") literally. Pozen also alleges that Defendants Par and DRL directly infringe Claim 2 of U.S. Patent No. 7,332,183 ("the '183 Patent") under the doctrine of equivalents.

Pozen seeks a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Par and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Par or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under Abbreviated New Drug Application ("ANDA") No. 90-753 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent. Pozen also seeks a permanent injunction under 35 U.S.C. § 271(e)(4)(B),

restraining Defendant DRL and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with DRL or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-930 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent. In addition, Pozen seeks a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Alphapharm and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Alphapharm or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-872 until the expiration of the '499 Patent and the '458 Patent.

Moreover, Pozen seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Par's ANDA No. 90-753 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent. Pozen also seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant DRL's ANDA No. 90-930 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent. Further, Pozen seeks an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Alphapharm's ANDA No. 90-872 shall not be earlier than the expiration date of the '499 Patent and '458 Patent.

Defendants Par and DRL deny that they infringe, either directly or indirectly, any of the asserted claims of the '499 Patent, the '458 Patent, and the '183 Patent. Defendant Alphapharm denies that it infringes, either directly or indirectly, any of the asserted claims of the '499 Patent

and the '458 Patent. Defendants assert invalidity counterclaims and Defendants Par and Alphapharm assert inequitable conduct counterclaims.

D. CONTENTIONS OF THE PARTIES

Pozen's Contentions

1. Pozen contends that each of the Defendants directly infringes the asserted claims of the '499 Patent and the '458 Patent literally.

2. Pozen contends that Defendants Par and DRL directly infringe the asserted claim of the '183 Patent under the doctrine of equivalents.

3. Pozen contends that each of the Defendants indirectly infringes the asserted claims of the '499 Patent and the '458 Patent by inducing others to directly infringe.

4. Pozen contends that the claims of the '499 Patent, the '458 Patent, and the '183 Patent are each presumed valid under 35 U.S.C. § 282.

5. Pozen contends that the effective filing date of the '499 and '458 patents is August 16, 1996.

6. Pozen contends that the effective filing date of the '183 patent is December 26, 2002.

7. Pozen contends that the '499 Patent, the '458 Patent, and the '183 Patent are each valid under 35 U.S.C. §§ 1 *et seq.*, including but not limited to Sections 102, 103 and 112.

8. Pozen contends that, to the extent Defendants are able to establish a *prima facie* case of obviousness, there is sufficient evidence of objective considerations to overcome Defendants' allegation of obviousness.

9. Pozen contends that the '499 Patent, the '458 Patent, and the '183 Patent are each enforceable.

10. Pozen contends that no one involved in the prosecutions of the '499 Patent, the '458 Patent, and the '183 Patent committed inequitable conduct during the prosecutions of the '499 Patent, the '458 Patent, and the '183 Patent.

11. Pozen contends that it is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Par and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Par or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-753 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent.

12. Pozen contends that it is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant DRL and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with DRL or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-930 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent.

13. Pozen contends that it is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Alphapharm and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Alphapharm or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United

States of a drug product under ANDA No. 90-872 until the expiration of the '499 Patent and the '458 Patent.

14. Pozen contends that it is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Par's ANDA No. 90-753 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent.

15. Pozen contends that it is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant DRL's ANDA No. 90-930 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent.

16. Pozen contends that it is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Alphapharm's ANDA No. 90-872 shall not be earlier than the expiration date of the '499 Patent and the '458 Patent.

Defendants' Contentions

1. Par contends it does not infringe the asserted claims of the '499 Patent and the '458 Patent either directly or indirectly by inducing others to infringe.

2. Alphapharm contends it does not infringe the asserted claims of the '499 Patent and the '458 Patent either directly or indirectly by inducing others to infringe.

3. DRL contends it does not infringe the asserted claims of the '499 Patent and the '458 Patent either directly or indirectly by inducing others to infringe.

4. Par contends that it does not directly infringe the asserted claim of the '183 Patent under the doctrine of equivalents.

5. DRL contends that it does not directly infringe the asserted claim of the '183 Patent under the doctrine of equivalents.

6. Defendants contend that the '499 and '458 patents are not entitled to an effective filing date of August 16, 1996.

7. Defendants contend that the asserted claims of the '458 Patent are invalid under 35 U.S.C. § 102 as being anticipated by prior art.

8. Defendants contend that the asserted claims of the '499 Patent, the '458 Patent, and the '183 Patent are invalid under 35 U.S.C. § 103 as being obvious over the prior art.

9. Defendants contend that the asserted claim of the '499 Patent is invalid under 35 U.S.C. § 112, first paragraph for lacking written description.

10. Defendants contend the asserted claims of the '499 and '458 Patents are invalid under 35 U.S.C. § 112, second paragraph as being indefinite.

11. Par and Alphapharm contend that the '499 Patent, the '458 Patent, and the '183 Patent are each unenforceable due to inequitable conduct.

12. Defendants contend that Pozen is not entitled to any permanent injunction under 35 U.S.C. § 271(e)(4)(B).

13. Defendants contend that Pozen is not entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of any of the Defendants' ANDAs shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and/or the '183 Patent.

E. STIPULATIONS AND UNCONTESTED FACTS

1. Jurisdiction is proper in this Court.

2. Venue is proper in this judicial district.

The parties will continue to attempt to identify additional potential stipulations, including stipulations related to the truth and accuracy of exhibits, and will inform the Court to the extent that additional stipulations are agreed to by the parties.

F. CONTESTED ISSUES OF FACT AND LAW

Pozen's Contested Issues

1. Whether each of the Defendants have directly infringed any asserted claims of the '499 Patent and the '458 Patent literally.
2. Whether Defendants Par and DRL have directly infringed the asserted claim of the '183 Patent under the doctrine of equivalents.
3. Whether each of the Defendants have indirectly infringed any asserted claims of the '499 Patent and the '458 Patent by inducing others to directly infringe.
4. Whether the effective filing date of the '499 and '458 patents is August 16, 1996.
5. Whether the effective filing date of the '183 patent is December 26, 2002.
6. Whether the claims of the '499 Patent, the '458 Patent, and the '183 Patent are each valid under 35 U.S.C. §§ 1 *et seq.*, including but not limited to Sections 102, 103 and 112.
7. To the extent Defendants are able to establish a *prima facie* case of obviousness, whether there is sufficient evidence of objective considerations to overcome Defendants' allegation of obviousness.
8. Whether the '499 Patent, the '458 Patent, and the '183 Patent are each enforceable.
9. Whether anyone involved in the prosecutions of the '499 Patent, the '458 Patent, and the '183 Patent committed inequitable conduct during the prosecutions of the '499 Patent, the '458 Patent, and the '183 Patent.
10. Whether Pozen is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Par and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Par or any of the foregoing, from the

commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-753 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent.

11. Whether Pozen is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant DRL and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with DRL or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-930 until the expiration of the '499 Patent, the '458 Patent, and the '183 Patent.

12. Whether Pozen is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B), restraining Defendant Alphapharm and its affiliates, officers, agents, servants, employees, and any person in active concert or participation with Alphapharm or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States or inducing others in the manufacture, use, import, offer to sell or sale within the United States of a drug product under ANDA No. 90-872 until the expiration of the '499 Patent and the '458 Patent.

13. Whether Pozen is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Par's ANDA No. 90-753 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent.

14. Whether Pozen is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant DRL's ANDA No. 90-930 shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and the '183 Patent.

15. Whether Pozen is entitled to an order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendant Alphapharm's ANDA No. 90-872 shall not be earlier than the expiration date of the '499 Patent and the '458 Patent.

Defendants' Contested Issues

1. Whether each of the Defendants do not infringe the asserted claims of the '499 Patent and the '458 Patent either directly or indirectly by inducing others to infringe.

2. Whether Par and/or DRL do not directly infringe the asserted claim of the '183 Patent under the doctrine of equivalents.

3. Whether the asserted claims of the '458 Patent are invalid under 35 U.S.C. § 102 as being anticipated by prior art.

4. Whether the asserted claims of the '499 Patent, the '458 Patent, and the '183 Patent are invalid under 35 U.S.C. § 103 as being obvious over the prior art.

5. Whether there are sufficient secondary indicia of non-obviousness to overcome Defendants' showing of obviousness.

6. Whether the asserted claim of the '499 Patent is invalid under 35 U.S.C. § 112, first paragraph for lacking written description.

7. Whether the asserted claims of the '499 and '458 Patents are invalid under 35 U.S.C. § 112, second paragraph as being indefinite.

8. Whether the '499 Patent, the '458 Patent, and/or the '183 Patent are unenforceable due to inequitable conduct.

9. Whether Pozen is entitled to a permanent injunction under 35 U.S.C. § 271(e)(4)(B).

10. Whether Pozen is entitled to a order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of any of the Defendants' ANDAs shall not be earlier than the expiration date of the '499 Patent, the '458 Patent, and/or the '183 Patent.

G. WITNESSES

Pursuant to the Docket Control Order, the parties were required to identify lists of trial witnesses on or before August 27, 2010. Attached to this Order as Exhibits A and B (for Pozen) and Exhibits C and D (for Defendants) are the parties' lists of witnesses and deposition designations, objections, counter-designations and offers of optional completeness.¹

Each party will provide to the other party the name and order of any witness that it intends to call to testify, whether live or by deposition testimony, by no later than 6:00 p.m. two days before the day the witness is expected to testify. Objections to any such witness shall be provided by 6:00 p.m. the following evening.

Any witness not listed in the exhibits referenced above will be precluded from testifying absent good cause shown, except that each party reserves the right to call such rebuttal witnesses (who are not presently identifiable) as may be necessary, on reasonable notice to the opposing party.

H. EXHIBITS

Attached to this Order as Exhibit E is a list of Joint Trial Exhibits. Attached to this Order as Exhibits F and G (for Pozen and Defendants, respectively) are each side's Unique Trial

¹ Since depositions in this case are ongoing, deposition designations may continue to be supplemented.

Exhibit Lists. Each list sets forth numbered exhibits, with a description of each containing sufficient information to identify the exhibits.²

Neither party admits or vouches for the admissibility of any items on the opposing party's exhibit list or the Joint Trial Exhibit List.

Notwithstanding any contrary provisions in this Order, the parties will disclose and exchange copies of demonstrative and summary exhibits to be used in direct examination in accordance with the following procedure. The parties shall exchange, via electronic mail or hand-delivery, complete color representations of all demonstrative exhibits no later than 10:00 pm CST the day before they may be used in Court. This paragraph shall not apply to demonstratives to be used during cross-examination, created during testimony or argument at trial, or to the ballooning, highlighting or excerpting of documents marked as exhibits.

I. LIST OF ANY PENDING MOTIONS

1. Defendants' Joint Motion for Partial Summary Judgment of Invalidity of U.S. Patent No. 6,060,499 for Insufficient Written Description under 35 U.S.C. § 112, ¶ 1 (Docket Nos. 294, 309, 325).

2. Defendant Par's Motion to Exclude the Testimony of Thomas G. Wiseman, Esq. (Docket Nos. 292, 308).

3. Defendant DRL's Motion for Summary Judgment that U.S. Patent No. 7,332,183 is Not Infringed (Docket Nos. 268, 285, 300).

4. Defendant Par Pharmaceutical's Motion for Partial Summary Judgment of Noninfringement as to U.S. Patent No. 7,332,183 (Docket Nos. 267, 286, 299).

J. PROBABLE LENGTH OF TRIAL

Plaintiff believes the probable length of trial is 30 hours.

² The parties will exchange objections to exhibits on September 29, 2010.

Defendants believe the probable length of trial is 32.5 hours.

K. MANAGEMENT CONFERENCE LIMITATIONS

To date, the parties have not reached agreement upon any limitations on the trial, nor have such limitations been ordered by the Court. The parties anticipate further negotiations may take place concerning potential limitations, and will inform the Court to the extent that additional agreements are made.

L. CERTIFICATIONS

The undersigned counsel for each of the parties in this action do hereby certify and acknowledge, but only with respect to its own conduct and disclosures that:

(1) Full and complete disclosure has been made in accordance with the Federal Rules of Civil Procedure and the Court's Orders;

(2) Discovery limitations set forth in the Federal Rules of Civil Procedure, the Local Rules, and the Court's Orders have been complied with and not altered by agreement or otherwise;

(3) Each exhibit in the List of Exhibits herein:

(a) is in existence;

(b) is numbered; and

(c) has been disclosed and shown to opposing counsel.

Approved as to form and substance:

Dated: September 28, 2010

Respectfully submitted,

/s/ Stephanie Lollo

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this document was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by email and/or fax, on this the 28th day of September, 2010.

/s/ Stephanie Lollo